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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,426	03/25/2005	Ferdinand Hermann Bahlmann	P/2107-264	5804

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EXAMINER	
HEARD, THOMAS SWEENEY	
ART UNIT	**PAPER NUMBER**
1654	
MAIL DATE	**DELIVERY MODE**
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,426	BAHLMANN ET AL.	
	Examiner	Art Unit	
	Thomas S. Heard	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *44-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 44,48,49,56,57,61,62,63,67,68,72,73, and 88 drawn to method for the treatment of chronic renal failure, said method comprising administering a pharmaceutical composition comprising a subpolycythemic erythropoietin dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight to a subject in need of said treatment.

Group II, claim(s) 45, 50, 51, 58, 64, 69, and 89 drawn to method for the treatment of acute renal failure, said method comprising administering a pharmaceutical composition comprising a subpolycythemic erythropoietin dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight to a subject in need of said treatment.

Group III, claim(s) 46, 52, 53, 59, 65, 70, and 90 drawn to method for wound healing, said method comprising administering a pharmaceutical composition comprising a subpolycythemic erythropoietin dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight to a subject in need of said wound healing.

Group IV, claim(s) 47, 54, 55, 60, 66, 71, and 91 drawn to method for therapeutic treatment of a condition selected from the group consisting of hypercholesterolemia, diabetes mellitus, endothelium-mediated chronic inflammatory disorders, endotheliosis including reticuloendotheliosis, atherosclerosis, ischemic disorders of the extremities, preeclampsia, Raynaud's disease and pregnancy-induced hypertension, said method comprising administering a pharmaceutical composition comprising a subpolycythemic erythropoietin dosis corresponding to a weekly dosis of 1 to 90 international units (1U) EPO/kg body weight to a subject in need of said therapeutic treatment.

Group V, claim(s) 74, 75, and 76 a method for producing a transplantable endothelial cell preparation, which method comprises applying erythropoietin to an endothelial cell preparation. drawn to ***

Group VI, claim(s) 77 and 78, drawn to method for at least one of pretreating and further treating tissue or organ transplants, which method comprises applying erythropoietin to a tissue or organ transplant..

Group VII, claim(s) 81 and 82, drawn to method for producing at least one of vascular prostheses and heart valves, said method • comprising coating a vascular prostheses or a heart valve with erythropoietin.

Group VIII, claim(s) 83-86, drawn to method for at least one of stimulating physiological mobilization of endothelial progenitor cells, proliferation of endothelial progenitor cells, differentiation of endothelial progenitor cells to endothelial cells and migration of endothelial progenitor cells in the direction of an angiogenic or vasculogenic stimulus, which method comprises applying to the cells at least one of erythropoietin and a derivatives thereof in a subpolycythemic EPO-dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight..

Group IX, claim(s) 87, 92, 93, and 94, drawn to method for stimulating formation of endothelial tissue, which method comprises administering a pharmaceutical composition comprising a subpolycythemic EPO-dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight to a subject in need of said stimulation.

Group X, claim(s) 95 - 101, drawn to pharmaceutical composition for use in at least one of stimulating endothelial progenitor cells, stimulating formation of endothelial tissue, stimulating vasculogenesis and treating diseases or pathological states associated with a dysfunction of endothelial progenitor cells, said composition comprising at least one of erythropoietin, a derivative, an analog, a modification and a mutein thereof as an active ingredient in a subpolycythemic EPO-dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight, and at least one further active ingredient selected fi-om the group consisting ofVEGF, PIGF, GM-CSF, an HMG-CoA reductase inhibitor and an NO donor.

Group XI, claim(s) 102, drawn to method for stimulating vasculogenesis, which method comprises administering at least one of erythropoietin and derivatives thereof in a subpolycythemic EPO-dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight to a subject in need of said stimulation..

Group XII, claim(s) 103-107, drawn to method for therapeutic treatment of at least one of pathological states and diseases of the human or animal body, which are associated with a dysfunction of endothelial progenitor cells, wherein said method comprises administering erythropoietin in a subpolycythemic EPO-dosis corresponding to a weekly dosis of 1 to 90 international units (IU) EPO/kg body weight to a subject in need of said treatment..

The inventions listed as Groups I - XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They are not linked by a special technical feature.

The expression "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art cannot be considered to be a special technical feature. Because the method of treating chronic renal failure with EPO is wel known in the art by reference US Patent 7,232,797, it cannot be considered a special technical feature.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows and are related to the Elected Group (supra) that must be elected. Upon Election of Invention, Applicants are to further elect the species within that elected group, such as:

If claim 47 elected, chose a species from the plurality of diseases claimed.

Route of administration: oral, injectable, infusible, parenteral, intravenous, intramuscular, intracutaneous, subcutaneous, and pulmonary.

Pharmaceutical composition: aqueous solution, non-aqueous solution, powder, solution, a suspension, an emulsion and a tablet.

Further active ingredient is selected from the group consisting of VEGF, PIGF, GM-CSF, an HMG-CoA reductase inhibitor and an NO donor.

EPO: erythropoietin is human or animal erythropoietin, wherein the erythropoietin is selected from the group consisting of a derivative, an analog, a modification and a mutein (?) of erythropoietin.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. That is, **Applicant is required to elect a single embodiment wherein all variable are particularly defined**. For example, if Applicants elect Group X, Applicants are then to elect a single species from claim 97. If Applicants elects Group I, for example, Applicants are to elect a single species from 48 and 49, 56 or 57, 61-62, 67, a single species of 68 (further active agent?)The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 47, 49, 51, 53, 55, 56, 61, 67, 72, 76, 83, 92, and 97.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TSH

6/25/09
ANISH GUPTA
PRIMARY EXAMINER